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<p>(21) International Application Number: PCT/US96/13570 (22) International Filing Date: 19 August 1996 (19.08.96) (30) Priority Data: 08/517,259 23 August 1995 (23.08.95) US (71) Applicant (for all designated States except US): ORTHO HELIX LIMITED [US/US]; 1100 Nola Avenue, Barberton, OH 44203 (US). (72) Inventor; and (75) Inventor/Applicant (for US only): KAY, David, B. [US/US]; 331 Lake of the Woods Boulevard, Akron, OH 44333 (US). (74) Agents: SHUNK, Laura, F. et al.; Hudak & Shunk Co., L.P.A., Suite 808, 7 West Bowery Street, Akron, OH 44308-1133 (US).</p>		<p>(81) Designated States: AU, BR, CA, FI, HU, JP, KR, NO, SG, TR, US, European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE). Published <i>With international search report.</i></p>
<p>(54) Title: OPEN HELICAL ORGANIC TISSUE ANCHOR AND METHOD OF FACILITATING HEALING</p> <div data-bbox="474 1302 1198 1759"></div> <p>(57) Abstract</p> <p>The invention relates to a tissue anchor (10) which is an open helix (12) of biocompatible material having a slope of from 0.5 turns per centimeter to 10 turns per centimeter, a length from 3 mm to 75 mm, a diameter of from 1.5 mm to 11 mm, and an aspect ratio of from about 3 to about 5 to 1. The anchor can have a head (17) which is capable of securing or clamping tissue together, such as holding a suture in hole (19) to secure a ligament or tendon (28) to bone. The anchor can also have a head which causes an inward, compressive loading for use in fastening bone to bone, orthopedic plates to bone, or cartilage to bone.</p>		

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OPEN HELICAL ORGANIC TISSUE ANCHOR
AND METHOD OF FACILITATING HEALING

FIELD OF INVENTION

5 The present invention relates to tissue anchors as well as to methods of promoting healing or repairing hard or soft, living, organic tissue using an open helix anchor.

10 BACKGROUND OF THE INVENTION

 The present invention relates to an anchor (or connector) which can be used to fasten organic tissue in close proximity in order to afford the tissue the opportunity to heal. The anchor of the present invention can be
15 used to anchor and clamp dense, regular and/or dense, irregular connective tissue in place in relation to bone. The anchor can also be used for cartilage transplants, i.e., for holding cartilage in fixed relation to bone, and can also be used in bone as a buttress, such as for
20 buttress plating techniques, or to fasten pieces of bone together as a screw substitute.

 As compared to the prior art, the anchor of the present invention allows a method of holding together organic tissue with minimal disruption to the biological
25 environment or to the tissue itself. For example, prior art devices and methods customarily require a large hole for insertion of the anchoring device, causing not only structural damage to the implantation site, but also inflicting further trauma to the biological site such as
30 generating heat, introducing further possibility for infection, and destroying bone which may be needed to help heal the repaired area. Such trauma is amplified in cases where prior art devices malfunction during the implant procedure. Hooks or screws can get stuck and further
35 obscure the operating site or require tedious removal.

 The anchor of the present invention may be very useful for applications such as anchoring ligaments or tendons when performing soft tissue surgical reconstruction, ruptured tendons, or torn ligaments, in which the

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surgeon wants to reconstruct or repair connective tissue with respect to the bone.

The anchoring device functions to hold together the tissue (such as connective tissue to bone) for a relatively limited time frame, e.g., six to twenty-six weeks, during which time the biological system will heal.

The anchor of the present invention can be used with advantage in many of the same applications in which cancellous screws are used in addition to applications in which traditional prior art anchoring techniques are unsatisfactory. The anchor of the present invention is far less invasive to implant than cancellous screws or hook-style anchors, i.e., the implant has a minimized mass, the insertion point is small relative to the size of the implant, and the device involves minimal removal of native tissue. In addition, the area of bone which is needed to secure the present invention can be of poorer quality than for prior art devices.

Additionally, the anchor of the present invention can be removed and minimally reangulated in order to utilize the same surgical site. Prior art devices require a large hole (relative to implant size) to be drilled in order to implant the device, and once the hole is contaminated by malfunction or misalignment of the device, it is necessary to drill another hole far enough away to achieve stability in a new location. Given the surgical context, this is extremely inconvenient.

The anchor of the present invention can be used in methods of ligament, tendon, or other tissue repair. For example, the anchor can be used for a method involving cartilage transplant and it can be used alone or in conjunction with a plate for a method of buttressing bone where the quality of bone may be questionable due to trauma or degenerative disease. The anchor may be used in methods of fixation involving connective tissue repair and replacement and may be inserted using a plunge-handle or

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"T" handle inserter which utilizes longitudinal travel in order to achieve rotational insertion.

Specifically, the anchor is used in ligament or tendon repair in which a pilot hole, having a diameter
5 much smaller than the outer diameter of the helical anchor, is drilled in the cortex of the bone. The angle of implantation can be varied as necessary. The anchor is subsequently mounted or loaded into the insertion tool, threaded into the pilot hole, and screwed into the bone an
10 appropriate distance so that the anchor head can be accessed but is not obtrusive. The ligament or tendon is attached to the anchor, such as by suturing.

In addition, the anchor of the present invention can be used to anchor plates and is particularly useful in
15 instances where the bone is of poor quality. In one embodiment, a modular head is used. A particularly desirable head has an internal hex slot to permit the anchor to be implanted. In addition, the head has a transverse through slot to hold a suture. The head has a
20 low, rounded profile with a distal stem which fits inside a ring of the helix and is laser-welded thereto.

SUMMARY OF THE INVENTION

The anchor in accordance with the invention
25 comprises an open helical structure which is a constant or varied-diameter, elongate member, fiber, or filament comprised of a relatively rigid, biocompatible material such as a wire having a diameter which may vary optimally from about 0.2 millimeters to about 5.0 millimeters. The
30 length of the anchor will depend upon the particular application, but will range generally from about 3.0 millimeters to about 75.0 millimeters with the upper ranges being useful for buttressing techniques. The outer diameter of the helix will also vary in accordance with
35 the application, but it will range generally from about 1.5 millimeters to about 15.0 millimeters. A suitable rate of slope for the helix is from about 0.5 to about 10

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turns per centimeter. The aspect ratio of the helix, which as used herein means the ratio of the helix outer diameter to the fiber diameter, is an important ratio in order to achieve the proper stiffness to enable insertion and to firmly seat in the bone; a suitable range is 3.5 to 4.5.

Advantageously, the anchor of the present invention involves relatively simple, cost-effective manufacturing processes. The present anchor is also less intimidating to doctors and patients than prior art devices and can be used with simple, straight-forward instrumentation. Finally, since the device is relatively noninvasive, several can advantageously be used together in instances where more than one prior art device could not be used. It is preferred, but not necessary, that the helix has a constant circular diameter and a constant slope (meaning the rate of turn per unit of longitudinal length).

For its connective applications, the anchor includes an attachment head at one end which is suitable for securing the tissue or suture which is to be held. For example, in the case of a filamentary anchor, the anchor may have a hook, crossbar or eyelet. For applications in which the anchor secures rigid material such as cartilage or a buttressing plate, the head may have a surface which is designed to distribute the load evenly over the rigid material.

In a second embodiment, the anchor will have a modular head. For example, the helical anchoring portion may terminate at the superficial end in a post that will accommodate one of several head options. These head options may include a button, clamp, clip, snap, or rivet. At the other end, the anchor includes a cutting or self-tapping point.

In accordance with another embodiment of the invention, a buttressing system is provided which compris-

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es a plate having at least two through bores which are each engaged by an open-helix anchor.

In accordance with a method of the present invention, an anchoring site is surgically accessed, the
5 helical anchor is screwed into the anchoring site, and connective tissue is secured to the attachment head of the anchor.

In accordance with another method of the invention, a bone is buttressed by surgically accessing an
10 implant site, aligning a plate having at least one aperture over the site, and securing the plate to the implant site by inserting an open-helix anchor through the aperture and into the implant site to anchor the plate with respect to the implant site.

15

DESCRIPTION OF THE DRAWINGS

FIGURE 1 is an elevational view of the anchor device showing the attachment head in side elevation;

FIGURE 2 is a top view taken of FIGURE 1;

20 FIGURE 3 is an elevational view, similar to FIGURE 1, but showing the anchor rotated 90° to the right so that the attachment head is seen in an end view;

FIGURE 4 illustrates the pilot hole in the bone prior to insertion of the anchor;

25 FIGURE 5 illustrates an anchor in place in the cancellous portion of the bone with the attachment head projecting above the surface of the bone in order to allow attachment of the soft tissue to the anchor;

30 FIGURES 6 and 7 illustrate the tool which may be used for inserting the anchor;

FIGURE 8 is a cross-section of a second embodiment of the anchor having a modular head; and

FIGURE 9 is a top view of the head illustrating the slot in phantom.

35

DETAILED DESCRIPTION OF THE INVENTION

In accordance with the invention, FIGURES 1-3 illustrates the anchoring device in accordance with the invention enlarged to show the invention in detail generally at 10. The anchoring device 10 comprises an open helix 12 having a pointed insertion tip 14 at one end and an attachment head 15 at the other end.

Preferably, the anchoring device is comprised of a rigid, biocompatible material having a high-yield strength such as stainless steel or titanium. The device can also be made from a biodegradable material such as polyglycolic acid ("PGA"), polylactic acid ("PLA"), polydioxane hydroxy apatite ("PDA"), and the like. For example, the device 10 may be made from surgical-grade titanium or stainless steel wire having a wire diameter ranging from about 0.4 millimeters to about 3.0 millimeters, and more specifically from about 0.5 millimeters to about 2.0 millimeters, and most specifically from about 1.0 millimeters to about 2.0 millimeters. Optionally, the helix diameter may be of variable cross-section ranging from a smaller-diameter wire at the insertion tip to a larger-diameter wire near the attachment head 15.

The "slope" of the helix is used herein to mean the number of turns (i.e., one 360° rotation) per unit length and varies from about 0.5 turn per centimeter to about 10 turns per centimeter, and more specifically from about 0.5 turn to about 4 turns per centimeter, and most specifically from about 1 to about 2 turns per centimeter. The anchor generally comprises a length of helix sufficient to achieve from 0.75 to 4 complete 360° revolutions, or more specifically from about 1 to about 3 revolutions. Accordingly the length of the anchor for most general fastening or anchoring applications is from about 3 to about 18 millimeters, and more specifically from about 4 to about 15 millimeters, and most specifically from about 8 to about 15 millimeters. For plating or buttressing applications, the length of the anchor will generally

range from about 5 to about 75 millimeters, preferably from about 5 to about 40 millimeters and most preferably from about 10 to about 20 millimeters.

The overall outer diameter of the open helix portion 12 of the anchoring device 10 ranges from about 1.5 to about 11 millimeters, and more specifically from about 3 to about 9 millimeters, and most specifically from about 5 to about 7 millimeters. The wire is generally circular in cross-section, although it is envisioned that it may be angular such as diamond-shaped or rhombohedral.

It is important that the anchor have an aspect ratio of from about 3 to about 5, preferably from 3.5 to 4.5, and most preferably around 4. As used herein, aspect ratio means the ratio of the helix outer diameter to the wire diameter. If the ratio is too large, the device is too rigid, whereas if the ratio is too small, the device is overly flexible.

The attachment head 15 of the anchoring device 10 may vary according to the specific application. For example, it may be desirable to include a broader compression area for direct attachment of connective or soft tissue to bone, as compared to suture techniques involving suturing or wiring the soft tissue in place with respect to the anchoring device. Examples of attachment heads suitable for suturing or wiring connective tissue include crossbars, hooks and eyelets.

FIGURE 1 illustrates an attachment head 15 having a crossbar 17 which arches slightly above the last helical turn and is attached such as by spot welding 18 at the terminal end. It may be further preferable to include an opening 19 or cannulation in the crossbar to allow for cannulated surgical techniques (i.e., placement of the anchor over a positioned wire which may be subsequently removed). The opening may range in size from 0.5 millimeters to 1.5 millimeters depending on the application.

The device and method of the invention are illustrated in FIGURES 3-5. In particular, FIGURE 4

illustrates a section of bone generally at 20 having a cortex 22 and a cancellous portion 24. A pilot hole 25 has been drilled in the cortex 22 in order to ease insertion of the anchoring device 10. A countersink hole 26 through the cortex is also illustrated.

FIGURE 5 illustrates the anchoring device 10 as it has been partially implanted through the pilot hole 25 into the cancellous portion of the bone. In some instances where the cortex is particularly thin, a pilot hole may be unnecessary. The soft tissue is attached to the anchoring device when the device is in position such as by suturing or wiring to the attachment head 15 of the anchoring device 10.

FIGURES 6 and 7 illustrate an instrument which can be used for the implantation of the anchor in accordance with the present invention. Specifically, the instrument includes a central shaft 30 having a T-shaped handle 32 designed to allow the surgeon to easily grasp the handle 32 and rotate the shaft 30 to screw the anchor 10 into the bone through the optional pilot hole. The placement guide 34 includes a bottom surface 36 which can rest against the cortical surface where the anchor 10 is to be implanted. The guide 34 further includes an internal opening 38 having a diameter sufficient to receive the top portion of the anchor 10. The guide 34 further includes a bore 40 which provides a bearing surface for the shaft 30. At its lower end, the shaft 30 includes a head 42 having an internal slot 44 which receives the crossbar of the anchor 10 to enable the surgeon to apply torque to the anchor. The head 42 has an external diameter which cooperates with the internal diameter of the anchor 10. Optionally, the shaft 30 may also include a longitudinal, internal opening to receive a guide wire to allow for further cannulated surgical techniques.

During use of the anchor of the present invention, the attachment location is approached with standard surgical exposure. A pilot hole is drilled through the

near cortex only and a drill sleeve is used to protect surrounding soft tissues. The anchoring device 10 is inserted with an insertion tool such that the attachment head 15 is left out of the bone. The angle of insertion
5 may be perpendicular to the bone surface or at a 45° angle. A suture may be passed under the exposed crossbar 17 of the attachment head 15 once or twice, depending on the surgeon's choice. The attachment tool is then used to countersink the attachment head 15 below bone level. The
10 ligament or tendon is then sutured into place with a preferred suturing method such as Bunnell, whip, or modified Kessler. The wound is subsequently closed and the procedure is completed in standard fashion.

FIGURES 8 and 9 show a second embodiment of the
15 anchor 80 having a modular head 82 attached to a helix 84. The helix 84 engages the bone as shown in the earlier embodiments. This version rotates through 540° (1½ full rotations) and terminates at one end in a three-sided point 86. At the other end, the helix 84 is formed into
20 a ring 88 to form a seat for the head 82. The ring 88 may be a complete circle or less than a circle, so long as it forms a good seat for the head 82. Preferably the ring 88 is the same diameter as the helix and the head 82 has the same outer diameter as the ring in order to allow the head
25 to be countersunk into a plate or bone.

Preferably both the head 82 and helix 84 are formed of implant-grade stainless steel (such as SS 22-13-5). The head 82 has a low, rounded, top profile, projecting from about 0.02 to 0.2 inch, and preferably from 0.05
30 to 0.1 inch from the top surface of the helix ring 88. The head 82 also includes an internal hex opening 90 to receive an anchor driver. The head 82 also includes a transverse through slot 92 shown in phantom in FIGURE 9. The slot can be used to hold sutures in order to anchor
35 tendons or ligaments. On the opposite side, the head 82 includes a necked area or stem 94 which is a constant

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diameter cylinder welded or otherwise adhered along the bottom edge to the ring 88.

EXAMPLE

5 Six samples of surgical-grade, stainless steel bone anchors in accordance with the invention were placed in a sample of artificial cancellous bone. Two samples each had a total longitudinal length of about 20 millimeters. The other four samples each had total lengths of
10 about 13 millimeters. The outer diameter of all samples was 5 millimeters and the wire diameter was 1.5 millimeters. Both long samples and two short samples had attachment heads which were crossbars and were attached by heliarc spot welding. The other short samples had cross-
15 bar attachment heads which were not welded.

 Pullout tests were conducted using an MTS instrument. Straight, longitudinal pull was applied to the embedded anchors; this reproduced the least favorable condition for pullout characteristics. The results are
20 shown in the table below. "Displacement" refers to bending of the crossbar in the longitudinal direction.

TABLE I
PLASTIC DEFORMATION

25

SHORT/NON-WELDED	SHORT/WELDED	LONG/WELDED
Average 48 lbs. with 2 millimeters of displacement	Average 52 lbs. with 2.2 millimeters of displacement	Average 58 lbs. with 2.4 millimeters of displacement

30

All of the numbers represent desirable anchoring values.

 While in accordance with the patent statutes the best mode and preferred embodiment has been set forth, the
35 scope of the invention is not limited thereto, but rather by the scope of the attached claims.

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WHAT IS CLAIMED IS:

1. An organic tissue anchor comprising a rigid, biocompatible, elongate member which forms an open, helical structure having a length from about 3 millimeters to about 75 millimeters, an outer diameter of from about 1.5 millimeters to about 15 millimeters, a slope from about .5 to about 10 turns per centimeter having at a first end an insertion tip, and at a second end an attachment head which is capable of connecting organic tissue to said anchor.

2. An anchor according to Claim 1, wherein the elongate member is a filament having a diameter of from about 0.4 millimeters to about 3 millimeters and the anchor is from about 2 to about 20 millimeters in length.

3. An anchor according to Claim 2, wherein the filament has a diameter of from about 0.5 to about 2 millimeters and a length of from about 4 to about 18 millimeters.

4. An anchor according to Claim 3, wherein the filament has a diameter of from about 1 to about 2 millimeters and a length of from about 8 to about 15 millimeters.

5. An anchor according to Claim 4, wherein the filament comprises surgical-grade titanium, or stainless steel wire or a bioabsorbable material.

6. An anchor according to Claim 5, wherein the attachment head is capable of receiving a suture and comprises a crossbar or a hook or an eyelet.

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7. An anchor according to Claim 3, wherein the helix achieves from about 0.5 to about 20 complete 360° revolutions.

5 8. An anchor according to Claim 7, wherein the anchor achieves from about 1 to about 4 revolutions.

9. An anchor according to Claim 2, wherein the overall outer diameter of the helix is from about 1.5 to
10 about 11 millimeters.

10. An anchor according to Claim 1, wherein the attachment head is cannulated.

15 11. A device for buttressing a bone comprising plate means and at least one anchor means, said anchor means being capable of securing said plate means to said bone and comprising a rigid, biocompatible filament in the form of an open helix of a length from about 5 to about 75
20 millimeters, and a slope of from about 0.5 to about 10 turns per centimeter, with an overall outer diameter of from about 5 to about 11 millimeters.

12. A device according to Claim 11, wherein the
25 filament has a diameter of from about 0.3 millimeters to about 4 millimeters.

13. A device according to Claim 12, wherein the anchor includes a head which distributes a load to the
30 buttressing plate.

14. A device as set forth in Claim 13, wherein said head is cannulated.

35 15. A method of securing tissue comprising:
accessing a surgical site including a tissue anchoring site;

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implanting an open, rigid, biocompatible helix into said site, said helix having a length of from about 2 to about 75 millimeters, a slope from about 5 to about 10 turns per centimeter, and an outer diameter of from about 1.5 to about 11 millimeters; and
attaching a tissue to said anchor.

16. A method according to Claim 15, wherein said tissue is attached by suturing said tissue to said anchor.

17. A method according to Claim 16, wherein said anchoring site is in bone.

18. A method according to Claim 17, wherein a pilot hole is made in the bone prior to the insertion of the anchor in the bone.

19. A method according to Claim 18, wherein the tissue is a ligament or tendon.

20. A method of buttressing bone comprising the steps of:

accessing a surgical site including at least a first cortical surface; and

implanting at least one anchor into at least said first cortical surface, said anchor comprising an open helix having a length of from about 5 to about 75 millimeters, a slope of from about 0.5 to about 10 turns per centimeter, having at a first end an insertion tip and at a second end a head capable of applying a compressive force in the direction of the first end.

21. A method according to Claim 20, wherein said head is cannulated and further including the steps of using a guide wire to achieve initial bone alignment and

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subsequently implanting said anchor about said guide wire by means of said cannulation.

22. A method according to Claim 21, wherein
5 said method further includes a step of aligning a plate on said first cortical surface, said plate having an anchor aperture and said anchor being implanted through said aperture so as to secure said plate relative to the cortical surface.

10

23. A method as set forth in Claim 20, wherein
said bone further includes a second cortical surface spaced apart from said first cortical surface by cancellous bone and wherein said anchor extends from said
15 cortical surface to said second cortical surface.

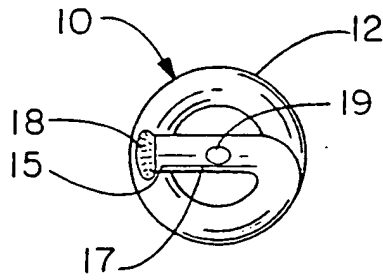


FIG. - 2

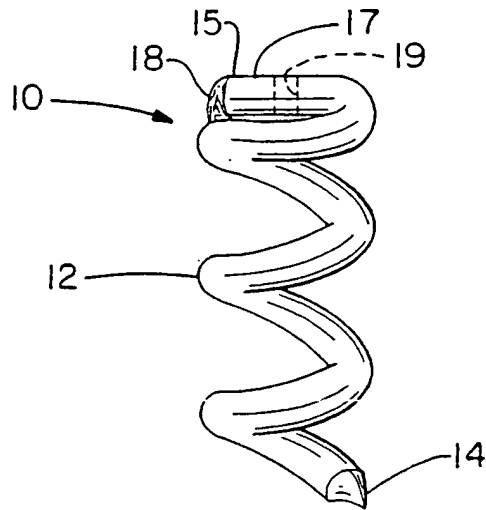


FIG. - 1

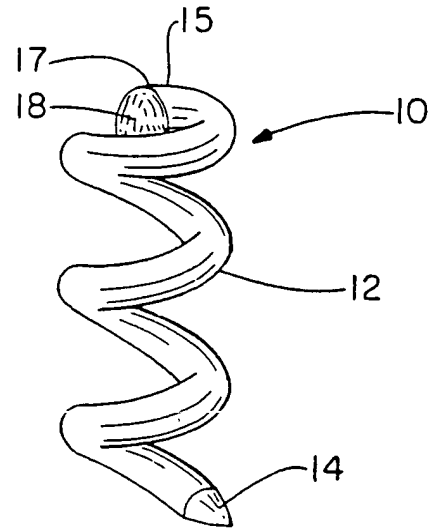


FIG. - 3

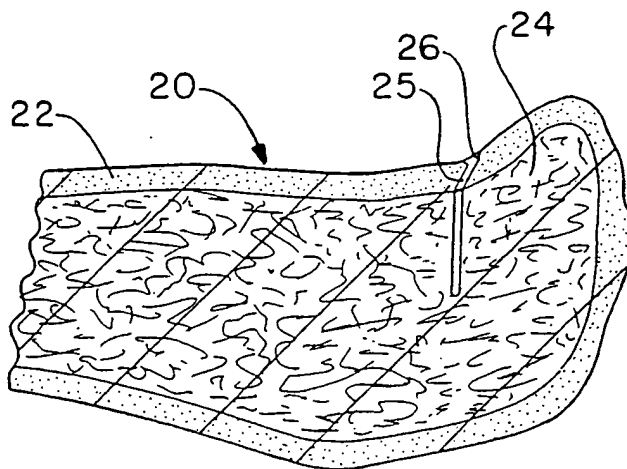
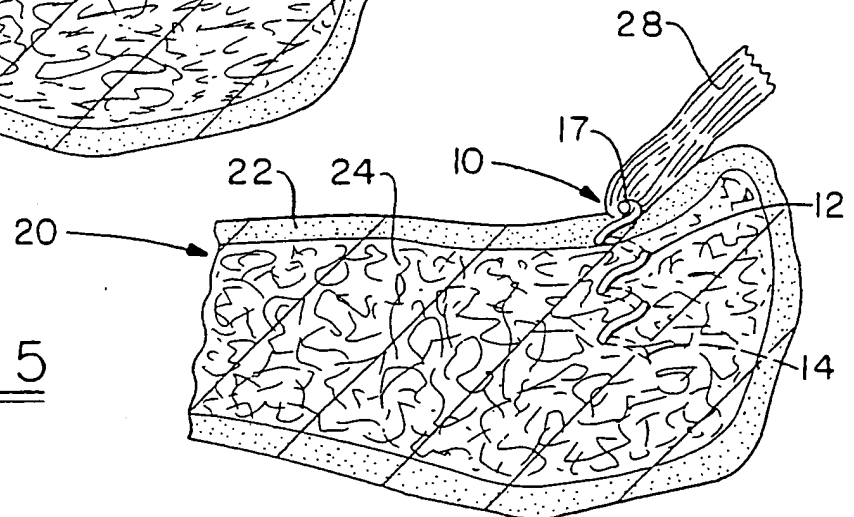


FIG. - 4

FIG. - 5



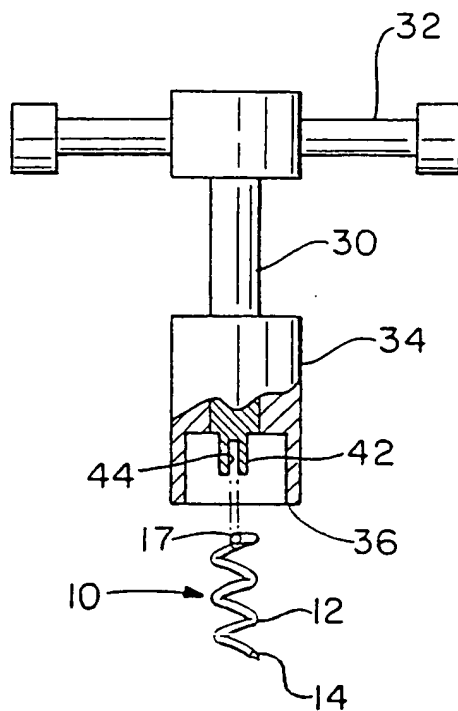


FIG.-6

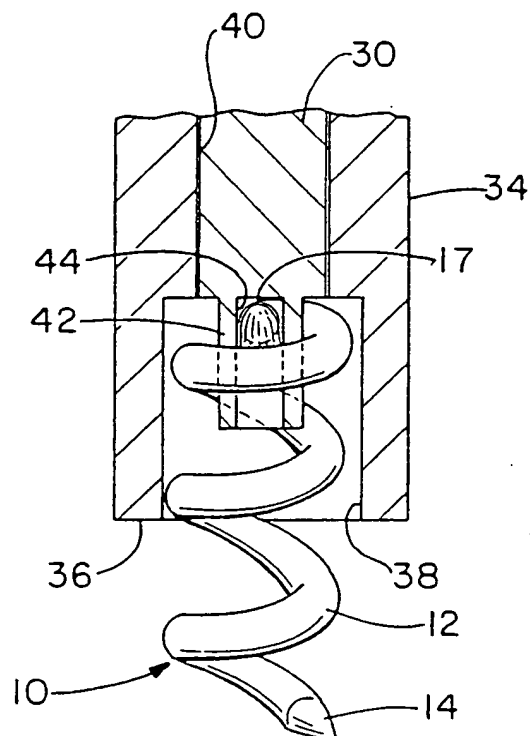


FIG.-7

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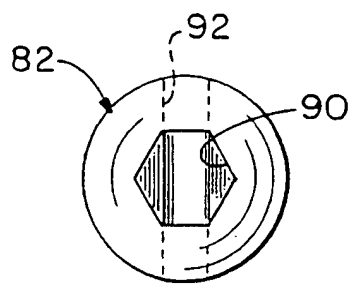
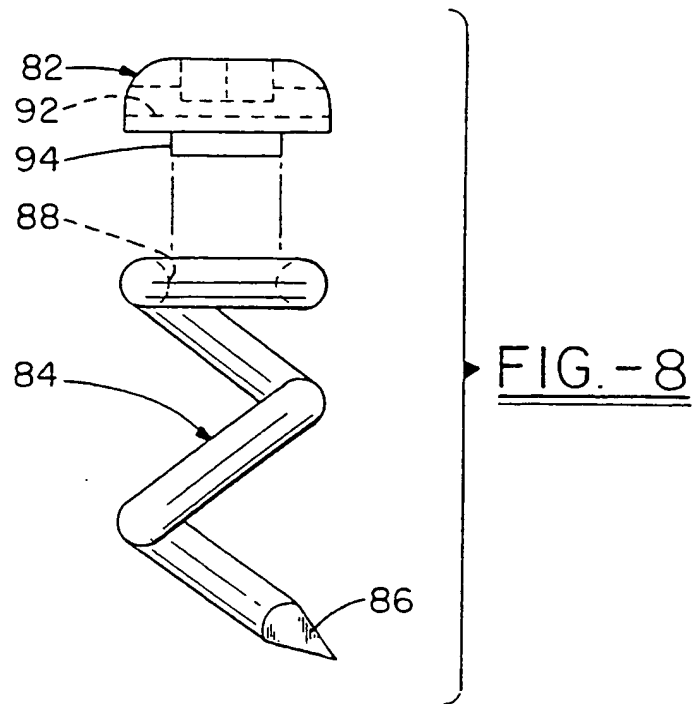


FIG. -9

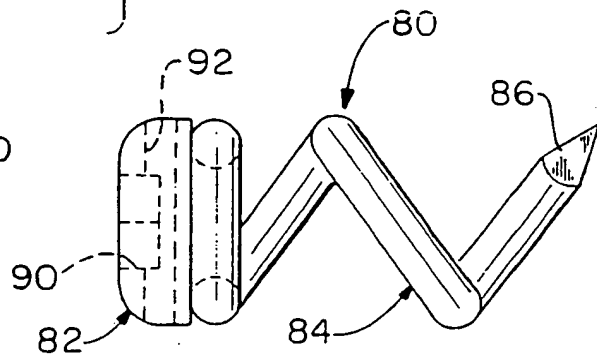


FIG. -10

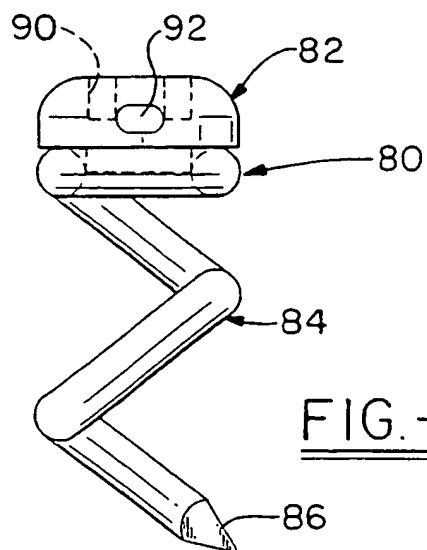


FIG. -11

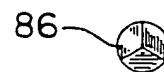


FIG. -12

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US96/13570

A. CLASSIFICATION OF SUBJECT MATTER IPC(6) : A61B 17/00 US CL : 606/151 According to International Patent Classification (IPC) or to both national classification and IPC		
B. FIELDS SEARCHED Minimum documentation searched (classification system followed by classification symbols) U.S. : 606/60, 65, 72, 73, 75, 151, 232 Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)		
C. DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	EP, A, 0 663 184 (ROSENMAN) 19 July 1994, see entire document.	1-16
X	WO, A, 94/28811 (ROGER) 22 December 1994, see entire document.	15-21
X	US, A, 2,414,882 (E. E. LONGFELLOW) 28 January 1947, see entire document.	20-22
X	US, A, 2,570,465 (J. S. LUNDHOLM) 09 October 1951, see entire document.	20, 21, 23
<input type="checkbox"/> Further documents are listed in the continuation of Box C. <input type="checkbox"/> See patent family annex.		
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Date of the actual completion of the international search 01 OCTOBER 1996	Date of mailing of the international search report <div style="font-size: 1.2em; font-weight: bold;">29 OCT 1996</div>	
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3590	Authorized officer <i>Diane L. Smith for</i> JEFFREY A. SCHMIDT Telephone No. (703) 308-3141	